



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 28, 2015

Cook, Inc.
Ms. Sarah Reeves
Regulatory Engineer
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

Re: K142829

- Trade/Device Name:
- 1) Flexor Tuohy-Borst Side-Arm Introducer, Ansel Modification
 - 2) Flexor Check-Flo Introducer, Ansel Modification
 - 3) Flexor Check-Flo Introducer, Ansel Modification with High-Flex Dilator and Hydrophilic Coating
 - 4) Flexor Check-Flo Introducer, Balkin Up and Over Contralateral Design
 - 5) Flexor Up and Over, Balkin Contralateral Introducer
 - 6) Flexor Check-Flo Introducer, Raabe Modification
 - 7) Flexor Check-Flo Performer Introducer

Regulation Number: 21 CFR 870.1340

Regulation Name: Catheter Introducer

Regulatory Class: Class II

Product Code: DYB

Dated: June 19, 2015

Received: June 22, 2015

Dear Ms. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)

K142829

Device Name

- 1) Flexor® Tuohy-Borst Side-Arm Introducer, Ansel Modification
- 2) Flexor® Check-Flo® Introducer, Ansel Modification
- 3) Flexor® Check-Flo® Introducers, Ansel Modification with High-Flex Dilator and Hydrophilic Coating
- 4) Flexor® Check-Flo® Introducer, Balkin Up and Over® Contralateral Design
- 5) Flexor® Up and Over®, Balkin Contralateral Introducer
- 6) Flexor® Check-Flo® Introducer, Raabe Modification
- 7) Flexor® Check-Flo® Performer Introducer

Indications for Use (*Describe*)

Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) Summary

Flexor® Tuohy-Borst Side-Arm Introducer Ansel Modification
Flexor® Check-Flo® Introducer Ansel Modification
Flexor® Check-Flo® Introducers Ansel Modification
with High-Flex Dilator and Hydrophilic Coating
Flexor® Check-Flo® Introducer
Balkin Up and Over® Contralateral Design
Flexor® Up and Over® Balkin Contralateral Introducer
Flexor® Check-Flo® Introducer Raabe Modification
Flexor® Check-Flo® Performer Introducer
Traditional 510(k)
510(k) Summary
21 CFR §807.92

Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	Sarah Reeves
Email:	sarah.reeves@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 105024
Contact Fax Number:	812-332-0281
Date Prepared:	18 June 2015

Device Information:

Device Trade Name:	Flexor® Tuohy-Borst Side-Arm Introducer, Ansel Modification Flexor® Check-Flo® Introducer, Ansel Modification Flexor® Check-Flo® Introducers, Ansel Modification with High-Flex Dilator and Hydrophilic Coating Flexor® Check-Flo® Introducer, Balkin Up and Over® Contralateral Design Flexor® Up and Over® Balkin Contralateral Introducer Flexor® Check-Flo® Introducer, Raabe Modification Flexor® Check-Flo® Performer Introducer
Common Name:	Introducer Set
Classification Name:	Catheter Introducer DYB (21 CFR §870.1340)



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Predicate Devices:

The subject devices are equivalent to the Pinnacle[®] Destination[®] Peripheral Guiding Sheath (K091329, 29 May 2009) and the Cordis Brite Tip[®] Catheter Sheath Introducer (K984500, 23 December 1998).

Comparison to Predicate:

It has been demonstrated that Flexor[®] Tuohy-Borst Side-Arm Introducer Ansel Modification, Flexor[®] Check-Flo[®] Introducer Ansel Modification, Flexor[®] Check-Flo[®] Introducers Ansel Modification with High-Flex Dilator and Hydrophilic Coating, Flexor[®] Check-Flo[®] Introducer Balkin Up and Over[®] Contralateral Design, Flexor[®] Up and Over[®] Balkin Contralateral Introducer, Flexor[®] Check-Flo[®] Introducer Raabe Modification and Flexor[®] Check-Flo[®] Performer Introducer are comparable to the predicate devices in terms of intended use, duration of use, principles of operation, technological characteristics, and insertion method. The devices subject of this submission and both predicate devices are intended to be used as introducer sheaths, allowing for the introduction of subsequent devices into the vascular system without the necessity of an additional vascular puncture or cut-down. All of these devices are composed of a proximal hemostasis component, a single lumen reinforced shaft, a distal tip in a curved or straight configuration and are provided with a dilator. Modifications to the proposed device include materials, including sheath, dilator, proximal fittings and hydrophilic coating, dilator wire guide compatibility, dilator extension length and shelf life.

Device Description:

The Flexor[®] Tuohy-Borst Side-Arm Introducer Ansel Modification, Flexor[®] Check-Flo[®] Introducer Ansel Modification, Flexor[®] Check-Flo[®] Introducers Ansel Modification with High-Flex Dilator and Hydrophilic Coating, Flexor[®] Check-Flo[®] Introducer Balkin Up and Over[®] Contralateral Design, Flexor[®] Up and Over[®] Balkin Contralateral Introducer, Flexor[®] Check-Flo[®] Introducer Raabe Modification and Flexor[®] Check-Flo[®] Performer Introducer are composed of an introducer sheath and a dilator(s). These devices are intended to be used as introducer sheaths, providing means of introducing therapeutic or diagnostic devices into the vasculature.



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The Flexor® Tuohy-Borst Side-Arm Introducer Ansel Modification includes a Tuohy-Borst polycarbonate proximal fitting and a straight or curved distal end. The dimensional range is 5-7 French in diameter and 55-90 centimeters in length. The shaft is composed of aTeflon lined, nylon, coil reinforced tubing. This product includes a hydrophilic coating and dilator.

The Flexor® Check-Flo® Introducer Ansel Modification includes a proximal silicone check-flo valve and straight or curved distal end. The dimensional range is 4-9 French in diameter and 45-110 centimeters in length. The shaft is composed of a Teflon lined, nylon, coil reinforced tubing. This product includes a hydrophilic coating and dilator.

The Flexor® Check-Flo® Introducers Ansel Modification with High-Flex Dilator and Hydrophilic Coating includes a proximal silicone check-flo valve and a straight or curved distal end. The dimensional range is 4-12 French in diameter and 45-110 centimeters in length. The shaft is composed of a Teflon lined, nylon, coil reinforced tubing. This product includes a hydrophilic coating and dilator.

The Flexor® Check-Flo® Introducer Balkin Up and Over® Contralateral Design includes a proximal silicone check-flo valve and a straight or curved distal end. The dimensional range is 5.5-12 French in diameter and 40-90 centimeters in length. The shaft is composed of a Teflon lined, nylon, coil reinforced tubing. This product may or may not include a hydrophilic coating. This product is provided with a dilator.

The Flexor® Up and Over® Balkin Contralateral Introducer includes a polycarbonate Tuohy-Borst proximal fitting and a curved distal end. The diameter range is 6-8 French. The shaft is composed of a Teflon lined, nylon, coil reinforced tubing. This product is provided in 45 centimeter length and includes a dilator.

The Flexor® Check-Flo® Introducer Raabe Modification includes a proximal silicone check-flo valve and a straight distal end. The dimensional range is 4-9 French in diameter and 55-90 centimeters in length. The shaft is composed of a Teflon lined, nylon, coil reinforced tubing. This product includes a dilator.

The Flexor® Check-Flo® Performer Introducer includes a proximal silicone check-flo valve and a straight distal end. The dimensional range is 5-12 French in diameter and 13-90 centimeters in length. The shaft is composed of a Teflon lined, nylon, coil reinforced tubing. This product contains a dilator.

**Intended Use:**

Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Test Data:

The proposed devices were subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, hemocompatibility, complement activation, and partial thromboplastin time) demonstrated that the device is biocompatible. In conformance with the applicable sections of ISO 10993-1:2009, the predetermined acceptance criteria were met.
- Coating integrity testing – Testing verified that there were no visible defects in the hydrophilic coating after insertion and withdrawal through a urethane sheet.
- Dilator and introducer sheath tensile testing – Testing verified that under proper clinical use of the dilator and introducer sheath, the peak load values shall be in accordance with the applicable values of BS EN ISO 11070:1999. The predetermined acceptance criteria were met.
- Dilator and introducer sheath liquid leakage – Testing verified that under proper clinical use of the dilator and introducer sheath, each test article shall not leak when tested in accordance with BS EN ISO 11070:1999, Annex D and E. The predetermined acceptance criteria were met.
- Dilator and introducer sheath mechanical abrasion – Testing verified that the hydrophilic coating met the requirements for durability. The predetermined acceptance criterion was met.
- Dimensional verification – Testing verified that the sheath and dilator met the dimensional requirements. The predetermined acceptance criterion was met.



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- Introducer sheath lubricity – Testing verified that while hydrated and subjected to a 300 gram normal force, the peak force over a 10 centimeter stroke shall be less than 100 gram during the course of 10 cycles. The predetermined acceptance criteria were met.
- Thromboresistance testing – Testing verified that there would be 0% to 25% estimated patency impact due to thrombus associated with the test articles. The predetermined acceptance criterion was met.
- Torque strength – Testing verified that the sheath withstood at least one full rotation before failure. The predetermined acceptance criterion was met.
- Acute Performance – Testing performed verified that performance parameters were acceptable for clinical use. The predetermined acceptance criterion was met.

In conclusion, the results of these tests support a determination of substantial equivalence.